PHILIP MORRIS U.S.A.

INTEROFFICE CORRESPONDENCE

Richmond, Virginia

Date: March 17, 1998

To: Jeff Sampson

From: Brent Chambers

Subject: **LIMS RFP Review from Systems Group**

The ITD systems group reviewed the LIMS Request for Proposal from the perspective of systems and network infrastructure. The LIMS RFP as written reflects a significant amount of work on the part of the LIMS team, and will clearly lead to the selection of an enterprise LIMS that meets R&D's needs. The following summarizes our comments, which we hope will assist in getting the best possible proposals to implement the LIMS system.

We had three key general comments:

- Storage or raw laboratory data needs to be addressed in some fashion, since the issue of whether this data is retained and how it will be retained are topics of continual discussion within R&D IS support.

- Systems requirements need to be consistently expressed in terms of our 'preferred' technologies (like DEC Unix) and 'preferred' capabilities (LIMS does not catastrophically fail when the network is down) rather than making any architecture requirements that may limit the vendors abilities to respond. Systems 'preferences' should reflect PMUSA, rather than only R&D.

- In general, the scope of the effort for the vendors needs to be more clearly defined. It appears the current status of the R&D LIMS project is that the selected vendor will do a pilot implementation in R&D, and barring a disaster, will then do the remainder of R&D. They will then be separately contracted to do a full-scale PMUSA implementation. This is not clear from the RFP as written, and is important to elicit the appropriate level of response from the vendors.

The following comments are (more or less) in order of the sections of the RFP.

1. Right in the introduction we should address issues of scope – (as mentioned above). The RFP should identify approximate number of labs, since the scope of work proposed by the vendors will reflect the scope asked for by the RFP. We want to "show them the money" up front.

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2. There appears to be a mismatch between the timeframes in the introduction and the LIMS project timeline (par. 4 says initial implementation must be completed by September 1, but the timeline shows Phase I going until February of 1999). If the timeline/GANT chart is to be delivered as part of the package, these should match up.

3. Section *IC3, System Preferences*:

- In section b. Protocols, we currently support X-windows and web-browser access. We are phasing out X-windows, but browsers should maybe also be mentioned as an acceptable GUI, if LAB support personnel agree.
- In section c. System Platform – preference will be given to systems that can run on hardware similar to current R&D/PMUSA standards, which includes Digital Alphas running DEC Unix or Windows NT, IBM RS6000s running AIX, or Compaq Intel Servers running Windows NT. Preference will be given to Sybase, Oracle, or other database systems that can exchange data with our current Sybase systems.
- In section c. par. 3 we refer to a historical archive. Are there expected sizes for this system? Will some sort of hierarchical storage system be part of the proposed LIMS solution? Probably need to add questions in section V. F. to the effect of: "How does your LIMS system handle historical data archiving? Does it interact with a hierarchical storage system? How does your LIMS historical archive address our varied document retention schedules?"

4. In section ***I.D. – Vendor Responsibility***, there should be a statement describing what support role the R&D IS staff will play in relation to the vendors installation team. Something like: Philip Morris R&D IS staff will assist vendor personnel with data migration and integration with existing lab systems. This is particularly important because the issue of ITDs role is not really clarified anywhere in the document.

5. Section *I.D.* may also be the appropriate place to put in a sentence to the effect that "Preference will be given to LIMS systems that do not require extensive customization or programming to support Philip Morris USA lab operations workflow."

6. Also in section *I.D.*, vendor responsibilities are said to include "training". This should be expanded to be "LIMS administration training and train-the-trainer training." Or "LIMS administration training for 5 IS personnel and LIMS user training for 130 scientists and technicians". What is our expected scope for training services from the vendor?

7. In section ***V.C. – Network Interactions*** – modify the first sentence to read "The users of the R&D LIMS are distributed across eight different buildings connected by a flat switched Ethernet network. PMUSA LIMS users will often be connected via slower-response wide area IP links. Interactions are ..." The question should then be: "Show, by means of previously established benchmarks for a similar system, the response of your system when clients and server components are distributed across a 10Mbs Ethernet network. Discuss the reaction of your system to a network disconnection or slow network response due to WAN links."

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8. In section ***V. F. 10 – Redundancy*** – it is not clear to us that it is necessary or appropriate for a LIMS system to keep on running in the event of a network failure. Some of our current LIMS systems are written entirely in a local store-and-forward fashion to allow this, but FDA and GLP may prefer that the LIMS user simply be notified that he cannot continue until the network is restored. In other words, if the database that stores standards and workflow procedures is not available, and the database to properly store, timestamp, and verify all the test results is not available – then the testing probably should not continue. It is certainly appropriate to ask the second two questions (how redundancy is handled, and how disaster recovery is handled). However, recommend you soften the language regarding transparent continued operations in the event of a network failure.

9. In section *V. G.* , suggest adding a question such as "How does your LIMS system handle raw test data?" or something to that effect. It would be important to at least know what the linkage is between LIMS test results and off-LIMS raw data, if there is any.

10. Also maybe in this section (*V.G.*) we should ask if the LIMS system lends itself to company-wide implementation at various locations – i.e., can it replicate standards tables, lab procedures, and codes across multiple installations, with each location maintaing separate lab data stores? Some sort of replication between sites is likely if this becomes a PMUSA-wide system.

11. Are the detailed requirements and flows in sections ***V. J-R*** appropriate to the rest of the company? The RFP may need to at least generally address how much of the detailed flows are relevant 'across PMUSA' and how much is specific to R&D.

12. In section ***V.R. 18*** – There is no need to mention the firewall, as current plans call for it to be eliminated prior to LIMS implementation.

Cc:
Bennie Good
Brian Kane
Robin Lipps
Jack Stimler
Jon Tabb
Dornan Trainer ✓
John Wickham

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